Fact Sheet for Veterinarians: Emergency Use Authorization of Credelio™ CAT (lotilaner)

Credelio™ CAT
(lotilaner)
Chewable Tablets
For oral use in cats

Original EUA Authorized Date: 11/21/2025

Emergency Use Authorization for CREDELIO CAT (lotilaner) for New World Screwworm (NWS)

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) for the emergency use of the approved product CREDELIO CAT (lotilaner) for the treatment of infestations caused by NWS (*Cochliomyia hominivorax*) larvae (myiasis) in cats and kittens. CREDELIO CAT is not approved for this use.

CREDELIO CAT is approved for other uses[1].

Limitations of Authorized Use

CREDELIO CAT (lotilaner) is authorized for this use only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of CREDELIO CAT (lotilaner) under section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

Justification for Emergency Use of Animal Drugs for NWS

The Secretary of the U.S. Department of Health and Human Services (HHS) has:

- Determined that there is a significant potential for a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad and that involves NWS (*Cochliomyia hominivorax*)[2].

- Declared that circumstances exist justifying the authorization of emergency use of animal drugs to treat or prevent NWS myiasis in animals.

[1] On December 9, 2019, CREDELIO CAT was approved to kill adult fleas and is indicated for the treatment and prevention of flea infestations (*Ctenocephalides felis*) for one month in cats and kittens 8 weeks of age and older, and weighing 2.0 pounds or greater. On April 12, 2021, CREDELIO CAT received a supplemental approval for the treatment and control of tick infestations [*Ixodes scapularis* (black-legged tick)] for one month in cats and kittens 6 months of age and older, and weighing 2.0 pounds or greater.
[2] See U.S. Department of Health and Human Services, Declaration of Emergency Pursuant to the Federal Food, Drug, and Cosmetic Act for New World Screwworm, August 20, 2025: https://www.federalregister.gov/documents/2025/08/20/2025-15918/declaration-of-emergency-pursuant-to-the-federal-food-drug-and-cosmetic-act-for-new-world-screwworm

An EUA is an FDA authorization for the emergency use of an unapproved product or unapproved use of an approved product (i.e., drug, biological product, or device) in the United States under certain circumstances including, but not limited to, when the Secretary of HHS declares circumstances exist justifying the product's emergency authorization, based on a determination, including but not limited to, a public health emergency or a significant potential for a public health emergency that may affect national security and that involves a biological agent[3].

Criteria for issuing this EUA include:

- The biological agent can cause a serious or life-threatening disease or condition;
- Based on the available scientific evidence (including data from adequate and well-controlled clinical trials, if available), it is reasonable to believe that:
    - The product may be effective in diagnosing, treating, or preventing the serious or life-threatening disease or condition; and
    - The known and potential benefits of the product - when used to treat such disease or condition - outweigh the known and potential risks of the product;
- There is no adequate, approved, and available alternative to the product for treating the serious or life-threatening disease or condition[4].

Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Description:
Refer to the package insert for full **Description** information.

Dosage and Administration:
CREDELIO CAT is given orally at the minimum dosage of 2.7 mg/lb (6 mg/kg).

Dosage Schedule:

Body Weight	Lotilaner Per Chewable Tablet (mg)	Chewable Tablets Administered
2.0 to 4.0 lbs	12	One
4.1 to 17.0 lbs	48	One
Over 17.0 lbs	NA	Administer the appropriate combination of chewable tablets

CREDELIO CAT must be administered with food.

[3] Emergency Use Authorization of Medical Products and Related Authorities | FDA (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities)
[4] FDA's "New World Screwworm: Information for Veterinarians": https://www.fda.gov/animal-veterinary/safety-health/new-world-screwworm-information-veterinarians

CREDELIO CAT is not available as scored tablets. The effectiveness of the administration of less than full tablets has not been evaluated.

Risk-Benefit Consideration for Cats on Other Isoxazolines:

If a cat is currently receiving another isoxazoline product for routine ectoparasite control, veterinarians should consider administering CREDELIO CAT to cats diagnosed with NWS myiasis based on a risk-benefit assessment and the emergency nature of NWS myiasis treatment.

Information Supporting Emergency Use Authorization
Based on the scientific evidence available to FDA, including data from published scientific literature, it is reasonable to believe that CREDELIO CAT may be effective for the treatment of infestations caused by NWS (*Cochliomyia hominivorax*) larvae (myiasis) in cats and kittens, and the known and potential benefits of CREDELIO CAT outweigh the known and potential risks.

A study conducted by Han and Yasmin[5] evaluated the effectiveness of lotilaner[6] for the treatment of naturally acquired Old World screwworm (OWS, *Chrysomya bezziana*) myiasis in cats in Malaysia. Two client-owned cats with active myiasis caused by *Chrysomya bezziana* larvae were enrolled. The cats included a 3-year-old male intact cat with a wound on the left hind paw and a 9-year-old male neutered cat with a wound on the right cervical neck region. Both cats received a single oral administration of lotilaner at doses of either 6 or 26 mg/kg body weight, following the dose bands for the approved flea and tick indications. The study was a case report and did not include a control group.

After treatment, both cats were hospitalized for 10 and 11 days and wounds were cleansed and flushed with saline solution until re-epithelization occurred. The study demonstrated 100% larvicidal effectiveness against OWS (*Chrysomya bezziana*) at 24 hours post-treatment in both cats. There were no adverse reactions during the study.

A study conducted by do Vale et al.[7] evaluated the effectiveness of CREDELIO (lotilaner) for the treatment of naturally acquired NWS myiasis in dogs in Brazil. Eleven client-owned dogs with active myiasis caused by *Cochliomyia hominivorax* larvae were enrolled based on lesion severity and larval burden. All dogs received a single oral administration of CREDELIO using the dose bands for the approved flea and tick indications. The study did not include a control group. After treatment, the dogs were kept in individual kennels with a removable tray. The dogs were observed 2- and 6-hours post-treatment, at which times expelled larvae were collected and quantified. At 24 hours post-treatment, the remaining larvae were mechanically removed from the wound and counted. The study demonstrated 100% overall effectiveness (number of expelled live and dead larvae and dead larvae mechanically removed) against *Cochliomyia hominivorax* larvae at 24 hours post-treatment with expulsion of larvae of 80.5% and 93% at 2 and 6 hours after treatment, respectively. The mean larvicidal effectiveness was 41.1% at 24 hours. There were no adverse reactions during the study.

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[5] Han, HS, Yasmin, L (2020). *Chrysomya bezziana* (Diptera: Calliphoridae) infestation in two Malaysian cats treated with oral lotilaner. *Vet Dermatol*, 31:335-e87.
[6] Same formulation as CREDELIO CAT.
[7] do Vale TL, Costa AR, Miranda LM, Silva GF, Silva NCS, Lima TB, Chaves DP, Sager H, Lasmar PVF, Costa-Junior LM. Efficacy of lotilaner against myiasis caused by *Cochliomyia hominivorax* (Diptera: Calliphoridae) in naturally infested dogs. *Parasit Vectors*. 2023;16(1):86.

There are several limitations of the data supporting the benefits of CREDELIO CAT for the treatment of NWS infestations, as the available study in cats was conducted against a different parasite species (OWS). The Han and Yasmin study was conducted in a limited population of two cats naturally infested with Old World screwworm (*Chrysomya bezziana*) in Malaysia, and the inferential value to the United States population and NWS species is unknown. Additionally, the case report design, lack of a control group, and demonstrated effectiveness in a different parasite species (*Chrysomya bezziana* vs. *Cochliomyia hominivorax*) limits the ability to define a pure treatment effect. The do Vale et al. study was conducted in a limited population of eleven naturally infested dogs in Brazil, and the inferential value to cats is unknown; however, the study used the approved lotilaner dose for the flea and tick indications. In that study, the primary mechanism of action against *Cochliomyia hominivorax* appears to be live larval expulsion. Additionally, the use of mechanical removal coupled with the lack of a control group confound the ability to define a pure treatment effect.

The available clinical data supporting the effectiveness of CREDELIO CAT against OWS (*Chrysomya bezziana*) larvae, and the effectiveness data for lotilaner in dogs against NWS, along with the established safety profile, support the potential benefit of CREDELIO CAT in the authorized patient population for the treatment of infestations caused by NWS larvae.

Contraindications:
There are no known contraindications for the use of CREDELIO CAT.

Warnings:
Not for human use. Keep this and all drugs out of the reach of children. Keep CREDELIO CAT in a secure location out of reach of dogs, cats, and other animals to prevent accidental ingestion or overdose.

Precautions:
Lotilaner is a member of the isoxazoline class. This class has been associated with neurologic adverse reactions including tremors, ataxia, and seizures. Neurologic adverse reactions have been reported in cats receiving isoxazoline class drugs, even in cats without a history of neurologic disorders. Use with caution in cats with a history of neurologic disorders.

The safe use of CREDELIO CAT in breeding, pregnant, or lactating cats has not been evaluated (see **Foreign Market Experience** on package insert).

The safety of CREDELIO CAT has not been evaluated in cats less than 8 weeks of age or less than 2.0 lbs.

Adverse Reactions:
Refer to the package insert for full prescribing information, including **Animal Safety**, **Adverse Reactions**, and **Post-Approval Experience**.

As described in the Letter of Authorization, veterinary facilities and veterinarians must report all **SERIOUS ADVERSE EVENTS*** potentially related to CREDELIO CAT use under this EUA (1) by contacting Elanco US Inc. at 1-888-545-5973, (2) by downloading and submitting Form FDA 1932a available at https://www.fda.gov/reportanimalae, or (3) contacting FDA at 1-888-FDA-VETS to request this form.

When reporting adverse events on Form FDA 1932a, include the following elements when applicable and/or available:

- Patient demographics (e.g., age, species and breed, sex, weight)
- The statement "CREDELIO CAT use for NWS under an EUA" under the "**Describe Adverse Event/Product Problem/Event Use Error"** heading
- Information about the serious adverse event (e.g., signs and symptoms, test/laboratory data, timing of drug administration in relation to the occurrence of the event, duration of the event, treatment required to mitigate the event, evidence of event improvement/disappearance after stopping/reducing the dosage, evidence of reappearance after reintroduction, clinical outcomes).
- Patient's pre-existing medical conditions and use of concomitant products
- Information about the product (e.g., dosage, route of administration, NDC#)

*Serious adverse events are defined as:

- Death
- A life-threatening adverse event
- An event that causes an abortion, stillbirth, or infertility
- A congenital anomaly or birth defect in offspring of treated animals
- A prolonged or permanent disability (e.g., persistent or significant incapacity or disruption of normal life functions)
- An event that requires professional intervention (e.g., important medical events that may require a medical/surgical intervention to prevent a death, life-threatening event, hospitalization, disability)

Reporting of lack of effectiveness, nonserious adverse events, or product quality defects is strongly encouraged via the mechanisms and including the information identified above for **SERIOUS ADVERSE EVENTS**.

Additional Information for Veterinarians:

Veterinary facilities and veterinarians will ensure that they are aware of and adhere to the terms of the Letter of Authorization. Fact Sheets will be made available to veterinarians.

Veterinary facilities and veterinarians will ensure that the client is aware that the drug is authorized for emergency use, but not approved, for the treatment of NWS myiasis and advise the client of the risks, benefits, and any alternatives.

Veterinary facilities will maintain health records that include the following information: client name, patient name, patient age, disease manifestation, number of doses prescribed or administered per patient, lot number prescribed or administered, and other drugs co-administered. The records shall be maintained in a manner that allows veterinary facilities to identify in a reasonable time which patients received drugs subject to this EUA.

Veterinary facilities will maintain any health records for the authorized use in this Letter of Authorization for at least two years following the termination or revocation of the EUA, or until notified by HHS, or FDA, whichever is sooner. Such records will be made available to Elanco US Inc., HHS, and FDA for inspection upon request.

Additional Information for Client (e.g., Animal Owner):

The lifecycle for *C. hominivorax* is as short as 21 days and wounds can be rapidly infested. Proper wound care and management practices are essential for preventing NWS myiasis. Cats may become reinfested following treatment.

Clients should be advised that:

- Gloves should be worn if cleaning the wound or the cat's bedding or disposing of larvae.
- Cats should be housed to prevent exposure to NWS flies until wounds have fully healed.
- Live larvae may exit the wound and be deposited on bedding or areas where the cat sits or lies after treatment.
- If expelled larvae are seen, clients should place the larvae in a sealed container with rubbing alcohol.
- If there is worsening of the wound, the client should contact the veterinarian.

How Supplied:
CREDELIO CAT is available in two chewable tablet sizes for use in cats: 12 and 48 mg lotilaner. Each chewable tablet size is available in color-coded packages of 1 chewable tablet. The 48 mg chewable tablet size is also available in color-coded packages containing 3 or 6 chewable tablets.

Storage Information:
Store at 15-25°C (59-77°F), excursions permitted between 5 to 40°C (41 to 104°F).

Manufactured for:
Elanco US Inc.
Greenfield, IN 46140 USA
CredelioCAT.com

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